## REMARKS

Claim 1 has been amended to incorporate the limitation of original claim 12, claim 3 has been amended to clarify that the device itself is generally planar shaped and claims 2, 11 and 15 have been amended to specify SIS is small intestine submucosa. Claim 18 has been added and support for that claim is found on page 2, lines 29-32.

Claims 1, 12 and 14 stand rejected under 35 USC 102(b) as being anticipated by Vacanti et al. (US 6,027,744). Applicants respectfully traverse.

Vacanti is directed to various hydrogel based compositions that are synthesized *in vitro*. More particularly, Vacanti teaches forming a hydrogel-cell composition, defined by Vacanti (in column 3, lines 17-18) as a suspension of a hydrogel, containing desired tissue precursor cells. The organic polymers of the hydrogel are then "solidified" to create a three dimensional open-lattice structure that entraps the cells. The solidified hydrogel-cell composition is then inserted into a "support structure" that maintains the structural integrity and desired shape of the hydrogel-cell composition.

Vacanti et al. fail to teach or suggest a composition comprising a sheet of naturally occurring extracellular matrix, as is claimed in the present compositions. Applicants note that the term "naturally occurring extracellular matrix" has been defined within the specification and that definition excludes man-made reformulated matrices such as the hydrogel compositions described in Vacanti et al. In particular, beginning at line 16 of page 3 of Applicants' specification, a naturally occurring extracellular matrix is defined in part as follows:

> For the purposes of this invention, it is within the definition of a naturally occurring ECM to clean, delaminate, and/or comminute the ECM, or even to cross-link the collagen fibers within the ECM. **However, it is not within the definition of a naturally occurring ECM to extract and purify the natural fibers and refabricate a**

> **matrix material from the purified natural fibers.** (emphasis added)

Vacanti discloses the formulation of a "hydrogel" matrix that entraps an isolated cell population. Such an *in vitro* refabricated matrix clearly falls outside the definition of a naturally occurring extracellular matrix. Simply state, Vacanti fails to teach or suggest a composition that comprises a naturally occurring matrix as required by independent claim 1.

The Examiner has stated that the claims are to be given their broadest reasonable interpretation. However, applicants respectfully submit that the claims are to be read in light of the specification, taking into account any definitions of claim terminology. As noted in the first sentence of MPEP 2111, "during examination proceedings, claims are given their broadest reasonable interpretation ***consistent with the specification.***" *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000) (emphasis added). This passage instructs Examiners that claims cannot be construed in a vacuum, but rather must be given an interpretation consistent with the specification. The drafters of the MPEP also looked to *Morris*, as its teachings are also cited in MPEP 2111:

> Since it would be ***unreasonable*** for the PTO to ignore any interpretive guidance afforded by the applicant's written description, either phrasing connotes the same notion: as an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, ***taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.*** *In re Morris*, 1054-1055 (emphasis added).

In the present application, Applicants have set forth a clear and express definition of the term "naturally occurring extracellular matrix (ECM)" on page 3 of Applicants' specification.

Accordingly, applicants respectfully submit it is not reasonable to give the claim term "naturally occurring extracellular matrix" a broader meaning than the meaning applicants have clearly provided for that term. Vacanti teaches the isolation of individual components and reformulating those purified components *in vitro* to form a matrix. The *de novo, in vitro* formed hydrogel matrix disclosed by Vancanti is clearly not a naturally occurring extracellular matrix in accordance with the definition provided on page 3 of Applicants' specification. Therefore, the compositions disclosed by Vacanti et al. fail to anticipate the present invention. Withdrawal of the rejection of claims 1, 12 and 14 as being anticipated by that reference is requested.

Claims 1-5, 7, 8, 11 and 15 stand rejected under 35 USC 102(b) as being anticipated by Buirge et al. (US 6,027,744). Applicants respectfully traverse.

Buirge et al. is directed to stents that are covered with a layer of collagen material. As described in the specification and the drawings the disclosed stents are tubular shaped and in accordance with column 3, lines31-40, typically comprise metal, a metal alloy or a suitable polymeric plastic. Such stents are used for maintaining vascular pendency in humans and animals. Thus the stent must be formed of a material that provides sufficient stability and strength to prevent the vessel from collapsing.

The present claimed compositions are formed from bioabsorbable components and claims 1 and 15 have been amended to specifically state that the sheet of synthetic mesh is bioabsorbable. Furthermore, the compositions of the present invention are formed using a sheet of naturally occurring matrix and a sheet of bioabsorbable synthetic mesh. Claim 3 has been further amended to emphasize that the device is generally planar in shape.

To anticipate a claimed invention, a prior art reference must disclose each of the elements of the claimed invention. Applicants respectfully submit the collagen material coated tubular

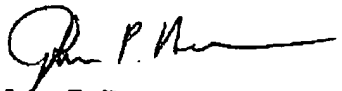
stents disclosed in the Buirge fail to anticipate the present claimed invention that includes a sheet of bioabsorbable synthetic mesh and a sheet of a naturally occurring matrix, wherein the construct is generally planar in shape.

Applicants respectfully submit that contrary to the Examiner's contention, Buirge does not disclose a "sheet of synthetic mesh." The only synthetic mesh disclosed by Buirge reference is a tubular stent. Furthermore, the Examiner seems to have equated the term "biocompatible" with "bioabsorbable." Applicants respectfully submit that it is not an inherent characteristic of biocompatible polymeric struts to be bioabsorbable. Nor is it inherent that a biocompatible polymer will have a rate of absorption slower than the extracellular matrix (as stated on page 3, last paragraph of the Office Action). Many biocompatible plastics are not bioabsorbable. Accordingly, Buirge fails to teach a composition comprising a sheet of bioabsorbable synthetic mesh wherein the mesh is coupled to the naturally occurring extracellular matrix.

Applicants respectfully submit the Buirge reference fails to anticipate the bioabsorbable compositions as claimed in the present invention and request the withdrawal of the rejection of claims 1-5, 7, 8, 11 and 15 as being anticipated by Buirge et al.

Applicants believe that the present application is now in condition for allowance and such action is respectfully requested. If the Examiner has any questions or comments such that a conversation would speed prosecution of this application, the Examiner is invited to call the undersigned at (434) 220-2866.

Respectfully submitted,



John P. Breen
Registration No. 38,833
Attorney for Applicants

(317) 261-7940
Indianapolis, Indiana 46204